

Our Vision is a U.S. military force that is fully sustained to fight and win in any CBRN battlespace worldwide.

Bioscavenger Pre-Solicitation Industry Day



October 14, 2011



Medical Identification & Treatment
Systems (MITS)

DISTRIBUTION STATEMENT A. Approved for public release;



Chemical Biological
Systems



AGENDA



0845-0855	Welcome/Introductions/ Rules of Engagement/ Review of Agenda
0855-0900	PTAC Overview
0900-1015	Overview of BSCAV Program and DRFP/Invite Written Questions
1015-1045	Break/Networking
1045-1200	Answer Written Questions
1200-1300	Lunch
1300-1315 One-on-One	Follow up Questions Answered/Rules of Engagement for





Ground Rules-Morning Session



- **Event is being recorded and will be and will be available as a pod cast next week**
 - Use microphones
 - Speak clearly
- **No sidebars in this meeting room**
- **Turn all phones and electronic devices off or set to vibrate**
 - Take calls into the lobby
- **Hold all technical questions/comments until Q&A portions (After Morning Break and After Lunch)**
 - Questions highly encouraged
 - Write questions/comments on cards, submit to Maria Dunton
 - Identify if proprietary
 - All non-proprietary questions/comments received prior to lunch will be addressed at the end of the day, if





Ground Rules-Afternoon Session



- **One on One meetings will be 15 minutes unless otherwise requested**
- **Companies who requested a one on one received their location and time at registration.**
- **The government will make time at the end of the day for vendors who wish to have additional time**
- **Companies not previously scheduled for a one on one, but wishing to participate should see Maria Dunton. The government will do what it can to accommodate all interested vendors.**
- **Simultaneous One on One Meetings will be conducted in the Astor and Commodore Perry Rooms**



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Bioscavenger Program Overview



October 14, 2011

MAJ Luis Alvarez, Ph.D.

Assistant Joint Product Manager

Medical Identification & Treatment Systems (MITS)

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Purpose



Purpose: To provide an overview of the Bioscavenger (BSCAV) program objectives and solicit feedback from industry on a draft request for proposals

Agenda:

- **MITS/CBMS/JPEO-CBD Mission**
- **BSCAV Program Overview**
- **Requirements Overview**
- **Government Furnished Information (GFI) Description**
- **Animal Rule & Countermeasure Development**
- **Draft RFP Overview**
- **Submitted Questions**





Disclaimer



- **Discussions today by Government officials involved in the Bioscavenger Acquisition should not be considered a guarantee of the Government's course of action in proceeding with the program**
- **The information shared today reflects current Government intentions and is subject to change based on a variety of circumstances including internal and external comments. The formal solicitation, when issued, is the only document that should be relied upon in determining, and responding to, the Government's requirements**





Introductions

Government Points of Contact



- **LTC Nanette Patton Joint Product Manager (JPM), MITS**
- **Dr. Renae Malek *Acting* Deputy JPM MITS, Chief Technical Officer**
- **Mr. Leo Fratis Contracting Officer, Army Contracting Command**
- **MAJ Luis Alvarez BSCAV Pharmaceutical Manager**
- **Mr. Brett Peterson BSCAV Senior Science Manager**
- **Ms. Mona Atkinson BSCAV Science Manager**





Rules of Engagement



- **Questions provided in writing via the Natick website by 11 October 2011 will be addressed**
 - Other questions shall be written on **index cards** and Government will reply as time permits
- **Official answers to questions will be published on the Natick website**
- **The final RFP will have adjudicating authority over anything discussed here that may be inconsistent with the draft RFP**
- **This brief will be posted on the Natick website**
- **No recording devices please**



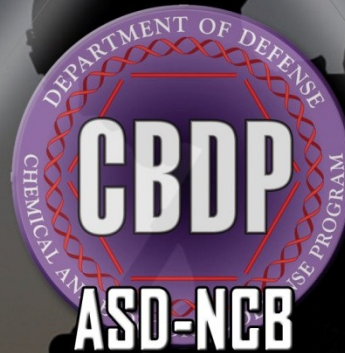


JPEO-CBD/CBMS/MITS Mission





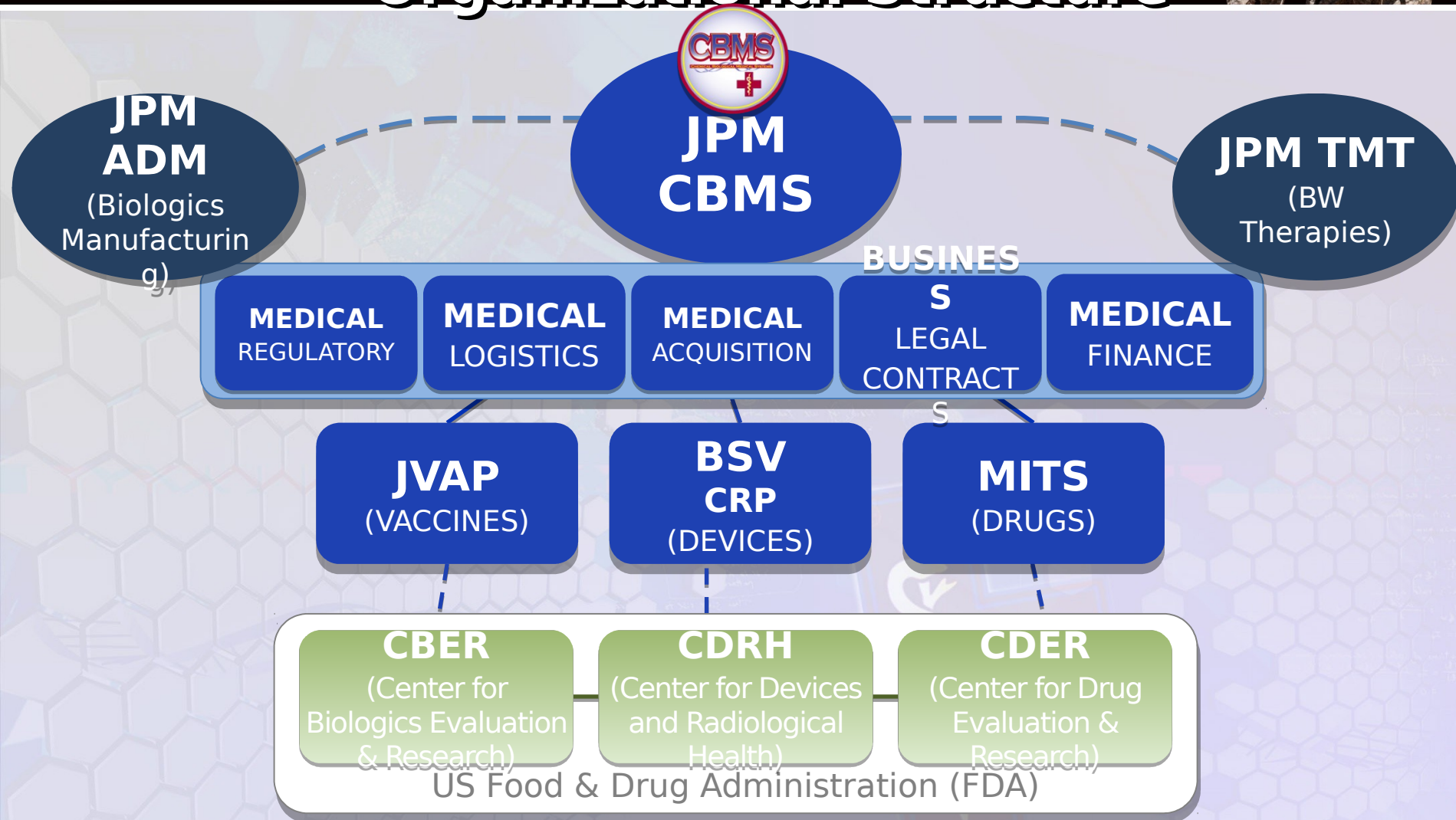
Joint Services Chemical Biological Radiological Nuclear (CBRN) Defense



DELIVERING JOINT WARFIGHTING CAPABILITIES



JPM-CBMS Medical Program Organizational Structure



— (Dotted line denotes coordination)



CBMS Program Overview



Our Vision is to protect the Warfighter by maintaining uncontested global supremacy in CBRN medical countermeasure development and delivery



Our Mission is to rapidly provide the Warfighter with safe, robust, affordable medical countermeasures against a broad spectrum of CBRN threats. Use government and commercial best practices to acquire FDA-approved CBRN





Warfighter Needs



Requirements Identified

Acquisition Documents

- Initial Capabilities Document (ICD)
- Capabilities Development Document (CDD)
- Capabilities Production Document (CPD)
- Key Performance Parameter = FDA Licensure



Science & Technology (S&T) Development

Advanced Development

FDA Licensure Process





Continuum of CBMS Medical Countermeasures



Biological Prophylaxis (Vaccines) are the highest rated Medical Counter-Measures on the "CBPM Capabilities Joint Priority List"

Focus on PREVENTION



DIAGNOSIS

TREATMENT



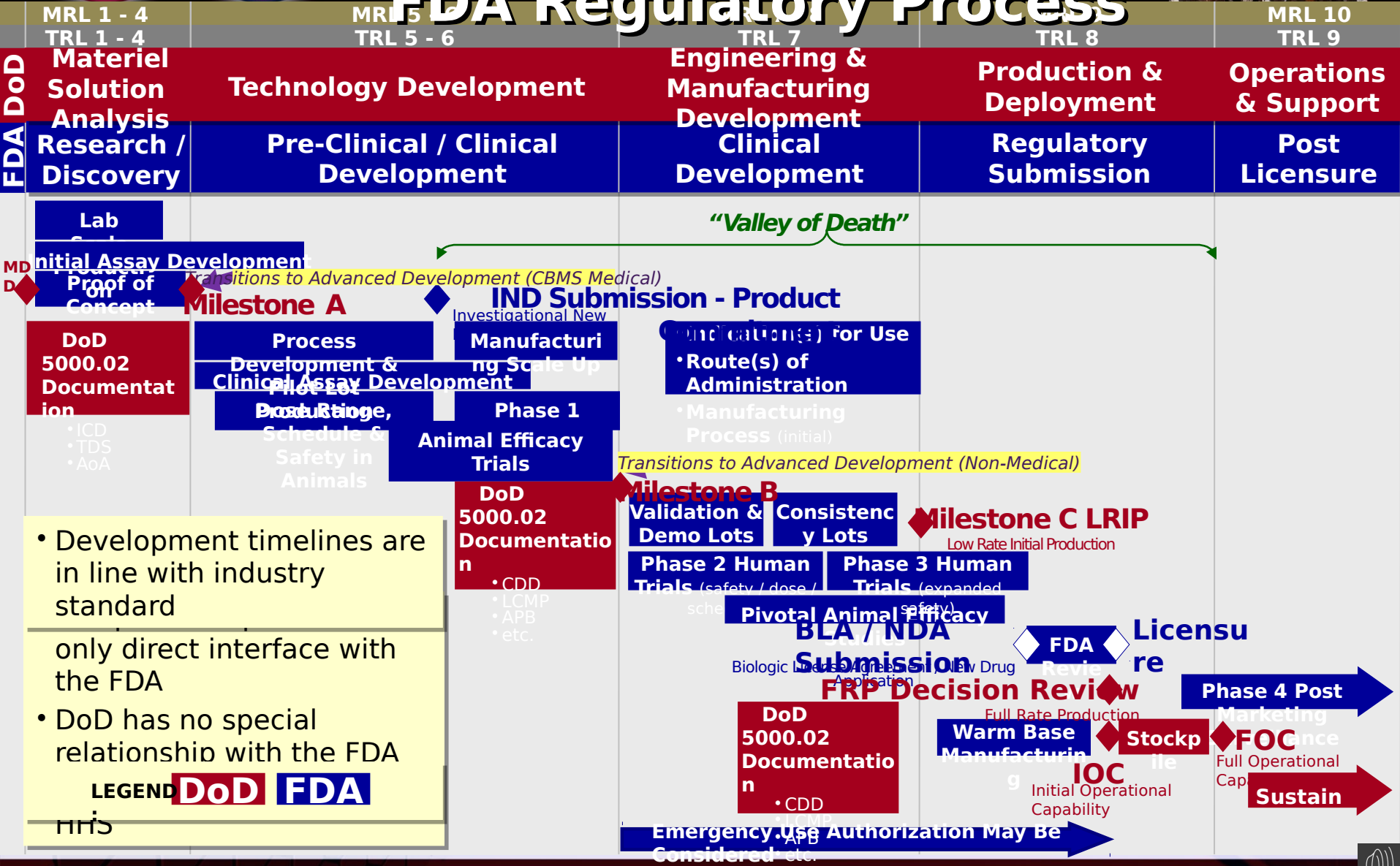
Prophylaxis preserves the fighting force

Treatment preserves life





Integration of DoD Acquisition Model & FDA Regulatory Process





Program Overview





MITS Portfolio



Bioscavenger is a prophylactic medical countermeasure regimen intended to prevent incapacitation and death from exposure to a broad spectrum of organophosphorus nerve





Improvement over Existing Treatment Regimen



- **Treatment regimen (post-exposure, post-symptomatic administration)**
 - Suite of products required, especially to achieve broad spectrum
 - SNAPP – pre-treatment in case of GD threat ($2LD_{50}$), requires subsequent treatment with ATR (atropine) / oxime (2-PAM) [ATNAA]
 - ATNAA and anticonvulsant (CANA: diazepam) – treatment initiated upon symptoms, within minutes of nerve agent exposure
 - Servicemember is a casualty; may suffer performance decrements and long term sequelae
- **Prophylactic regimen (pre-exposure administration)**
 - Stand alone product administered prior to nerve agent exposure
 - Broad spectrum protection against a broad range of organophosphorus nerve agents
 - Prevents nerve agent intoxication or extends lead time to react before becoming symptomatic
 - Protects central nervous system (CNS) by sequestering agent in





Requirements Overview





Capability Gap



- **There are insufficient medical products to adequately protect the operational force in all nerve agent threat environments**
- **Current FDA-approved pretreatments fail to provide comprehensive protection against the adverse effects of exposure to nerve agents**





DRAFT CDD Requirements



Key Performance Parameter	Threshold	Objective
Force Protection	Provide prophylaxis against the effects of a broad spectrum of traditional nerve agents	Provide prophylaxis against the effects of a broad spectrum of traditional agents
Regulatory Compliance	FDA-Licensure	
Key System Attributes	Threshold	Objective
Efficacy at Challenge Level	Protect 80% of treated force against an exposure of $2 \times LD_{50}$	Protect 90% of treated force against an exposure of $5 \times LD_{50}$
Time to Effect	Protection when administered 24 hours prior to exposure	Protection when administered 2 hours prior to exposure
Duration of Protection	Effective protection for 10 days	Effective protection for 60 days
Shelf Life	2 years	5 years
Storage Temperature	-20° to 0° C (frozen) or 0° - 10° C (refrigerated)	10° to 35° C (room temperature)
Additional Attributes	Threshold	Objective
# Doses	Three	One



Government Furnished Information (GFI)





Government Candidate



- **Government furnished candidate is human plasma-derived HuBChE**
- **A Technical Data Package for development of human plasma-derived butyrylcholinesterase (HuBChE) is provided in a bidder's library for potential offerors' reference**
- **Plasma-derived HuBChE has undergone animal toxicity and efficacy studies, a Phase 1 clinical trial and IND submission**
- **In animal studies, prophylaxis with plasma derived HuBChE protects against multiple LD₅₀s of all nerve agents tested for days to weeks**





Animal Rule & Countermeasure Development





Background - The Animal Rule



- **Allows for approval of medical countermeasures in which efficacy testing in humans is unethical**
- **Applies only when mechanism of agent is reasonably well understood**
 - Mechanism by which the product prevents disease or lessens effects of disease
 - Efficacy is demonstrated in more than one, well-defined animal model
 - Progression of the disease/condition should be similar to that of humans
 - Immunogenicity data in animals / humans allow for selection of an effective animal dose
 - Well controlled animal studies will provide data that are likely to predict a benefit in humans





The Animal Rule DOES NOT



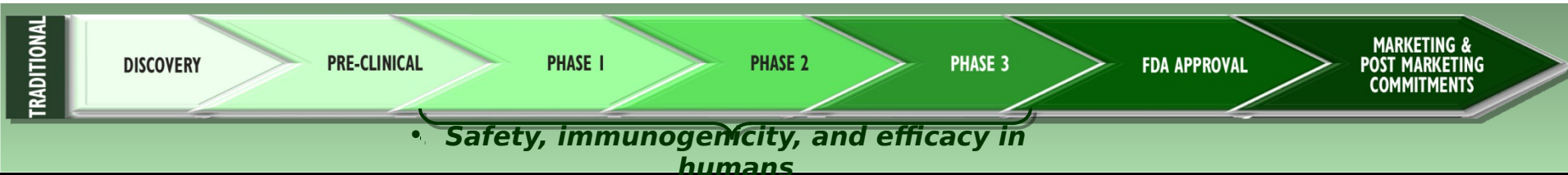
- **Apply to products when approval can be based on a demonstration of efficacy as described in other regulations**
 - 21 CFR 601.41 – accelerated approval based on surrogate markers or clinical endpoints other than survival or morbidity
- **Address evaluation of safety**
 - To be demonstrated in human volunteers – drugs/biologics licensed under the “Animal Rule” will still require a safety database of hundreds to thousands of volunteers (Expanded Safety and Immunogenicity Phase 3 clinical trial)
- **Accelerate the FDA licensure process**
- **Decrease the product development cost**



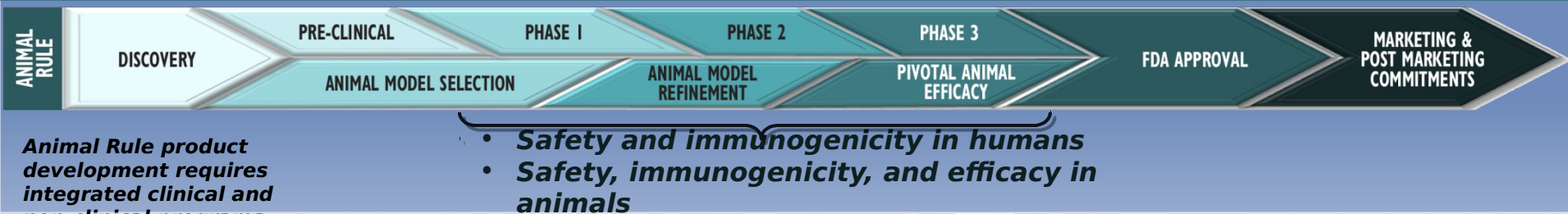
Product Development and the Animal Rule



TRADITIONAL LICENSURE PATHWAY



ANIMAL RULE LICENSURE PATHWAY



Animal Rule product development requires integrated clinical and non-clinical programs

- **Extensive Animal Model Development**
 - Efficacy is demonstrated in more than one, well defined animal model
 - Well controlled animal studies provide data that are likely to predict a benefit in humans



Draft FDA Guidance



Guidance for Industry Animal Models — Essential Elements to Address Efficacy Under the Animal Rule

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Rosemary Roberts, CDER, at 301-796-2210 or the Office of Communications, Training, and Manufacturers Assistance (CBER), 301-827-1800 or 800-835-4709.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2009
Pharm/Tox

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01/13/09



Draft RFP Overview

Leo Fratis
Contracting Officer





Solicitation / Contract Timeline



- **Pre-solicitation released 30 September 2011**
- **Pre-solicitation Industry Day, 14 October 2011**
- **Written answers to questions from Industry Day anticipated to be posted on the Natick website**
- **Final Request for Proposals (RFP) anticipated release date is in January 2012**
- **Proposals will be due 45 days from release of final RFP**
- **Contract award date projected on or about 4QFY12**





Request for Proposals (RFP)



Proposal Submission

- **Questions on final RFP will be permitted up to 2 weeks following release**
- **Submit and sign fully-executed RFP**
- **Complete Sections B (cost and share) through K**
- **Submit proposals in accordance with Section L of the RFP**
- **Turn-around of 45 days for proposal submission**





Request for Proposals (Cont)



Proposal Preparation Guidance

- **Use the templates provided in the RFP**
- **If bidding on government candidate utilize the Bidder's Library**
- **Proposals must conform to Section L criteria and map to the SOO for evaluation. Proposals must be complete or they may not be considered complete or responsible, and therefore not evaluated**
- **Demonstrate the offeror has a thorough understanding of requirements and inherent risks and is able to devote resources to meet the requirements and has a valid and practical**





Request for Proposals (cont.)



Proposal Preparation Considerations

- **Provide clear and concise descriptions / justifications**
- **Use the Evaluation Criteria to know where to place emphasis**
- **Ensure Evaluation Criteria, Proposal Instructions, and Proposal are consistent**
- **Can an evaluator quickly find what he/she needs?**
 - Is it clear? Well organized?
- **Substantiate, do not simply make claims**
 - Avoid making statements such as "we understand", "we are committed", "we are capable", "our experience ensures", etc.





Bidder's Library



- **Access to Bidder's Library**
 - The Bidder's Library is accessible at <http://bit.ly/ouUmHJ>; access will be granted upon completion of registration at the Army Knowledge Online (www.us.army.mil) website and sponsorship through a CBMS representative
- **Contents of Bidder's Library**
 - Government Furnished Information in the form of a Technical Data Package covering the development of plasma-derived HuBChE through Phase 1 clinical trial
 - Pertinent open source literature





Solicitation / Contract Form



- **Part I, Schedule**

- Section A Solicitation/Contract Form
- Section B Supplies or Services and Prices/Costs
- Section C Description/Specs/Work Statement
- Section D Packaging and Marking
- Section E Inspection and Marking
- Section F Deliveries or Performance
- Section G Contract Administration Data
- Section H Special Contract Requirements





Solicitation / Contract Form



- **Part II, Contract Clauses**
 - Section I Contract Clauses
- **Part III, List of Documents, Exhibits, and Other Attachments**
 - Section J List of Attachments
- **Part IV, Representations and Instructions**
 - Section K Representations, Certifications, and Other Statements of Offerors
 - Section L Instructions, Conditions, and Notices to Offerors
 - Section M Evaluation Factors for Award





Contractor Systems



- **Defense Contract Audit Agency (DCAA)**
 - Financial Accounting System
 - Estimating System
 - Purchasing System
 - Cost Accounting System
- **Defense Contract Management Agency (DCMA)**
 - Government Property System
- **Web-Based**
 - Central Contractor Registration (CCR)
 - DUNS
 - Wide Area Workflow (WAWF)
 - Invoicing/Receiving Reports
 - Online Representations and Certifications Application (ORCA)





Contract Award Overview



- **FAR Part 15 acquisition**
- **Contract type - CLIN Structure may include FFP, CPFF, or CPIF**
 - Minimum / Maximum Targets
 - Cost shares
 - Cost controls / Best effort
- **Anticipated Contract Award is scheduled for 4QFY12**





Contracting Approach Selection Criteria



**Chart 1 - Relative Ranking
of Evaluation Factors**
Note: Not to Scale

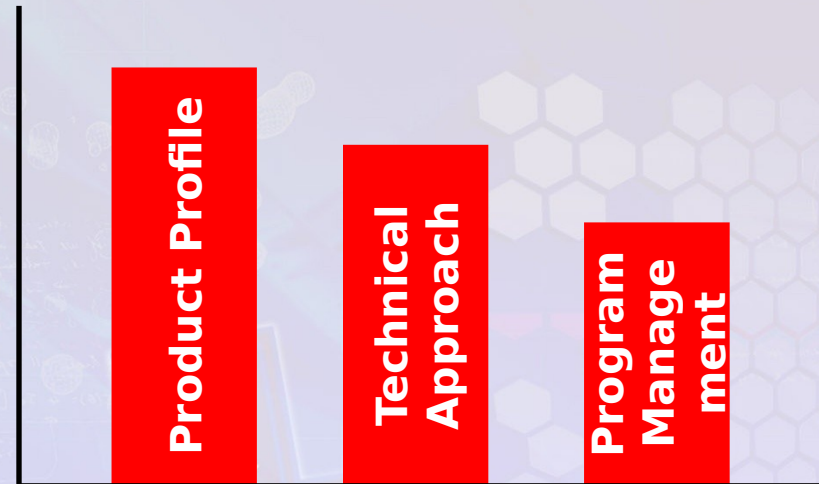


**Chart 2 - Relative Ranking
of Evaluation Factors:
Technical Subfactors**
Note: Not to Scale





Break





Submitted Questions





Technical Questions - RFP



- **Please define the level of detail required in the proposal. After initial consideration of the information solicited, the page limits do not appear to be sufficient. The draft RFP identifies the SOW, IMP, IMS, CWBS, EVMS, and QMP plan as separate documents. Will CBMS accept these as attachments in addition to the page limit for the section? Will CBMS consider increasing the page limits?**
 - *We will reconsider the page limits/structure for the final RFP.*
- **When will the bidder's library be accessible to potential offerors? Will it be updated as new technical data becomes available throughout the solicitation response period?**





Technical Questions - Acquisition Strategy



- **Please clarify that the contractor, not the government, will perform as the product sponsor to the FDA.**
 - *The contractor will be the product sponsor to the FDA.*





Technical Questions Period of Performance



- **For planning purposes, what is the anticipated period of performance for this effort?**
 - *This contract is an end item deliverable (a bioscavenger that has completed a successful FDA licensure) so period of performance is not applicable. Delivery schedule will be proposed by offerors.*
- **Are there expectations for Project duration through FDA licensure (i.e. 4-6 years)?**
 - *The project schedule will be that which provides the best overall value to the Government.*





Technical Questions



- **Assays will be critical for licensure under the Animal Rule. Will standard assays and reagents be provided to all Offerors?**
 - *Offerors should not assume that standard assays and reagents will be provided.*
- **What materials, data, reagents will be made available to a contractor developing the government owned bioscavenger candidate?**
 - *A technical data package will be available*





Technical Questions Pre-clinical



- **For each DoD-unique review or approval relative to animal welfare, please provide estimated duration(s) of government review/approval cycles for scheduling purposes.**
 - *Refer to the ACURO website (<https://mrmc.amedd.army.mil/rodorpaurd.asp>) for guidance on approval cycles.*
- **Is there an expectation that candidates be tested for efficacy in non-human primates prior to Phase 1?**
 - *The Offeror shall propose their best approach to accomplish the requirements of the RFP.*
- **Non-clinical requirements suggest that development of animal models to support the FDA animal rule would be required for this work. Is CBMS looking for a product development plan for licensing that would encompass all activities including the pivotal efficacy studies to be submitted with a response to the current RFP?**
 - *Animal model development work normally conducted concurrent to Phase 1*





Technical Questions Clinical



- **Please indentify any CBMS-MITS program office, or other DoD-unique reviews and approvals necessary for human subjects' protection.**
 - *Clinical protocols must be approved by the local Institutional Review Board (IRB) and the DoD Human Subject Research Review Board (HSRRB).*
<https://mrmc.amedd.army.mil/rodindex.asp>
- **For each CBMS-MITS/DoD-unique review or approval relative to human subjects' protection, please provide estimated duration(s) of government review/approval cycles for scheduling purposes.**
 - *Refer to the HSRRB website (*





Technical Questions - Clinical



- **Please identify the types and frequency of government review(s) and/or any government pre-approval(s) that will be required for contractor communications, meeting, and applications to FDA.**
 - *CBMS is to be involved in any communications with the FDA. All FDA regulatory submissions shall be reviewed by CBMS-MITS prior to filing by the Offeror and the final RFP will include review schedules.*





Contract Questions Past Performance



- **Past Performance requires detailed discussion of corporate relevant experience developing CBRN medical countermeasures and interacting with the FDA using the Animal Rule. Will the expertise of a subcontractor to the prime count toward total evaluation of this detail?**
 - *Yes, provided that is what the Subcontractor will do under the Proposal.*
- **Regarding the past performance questionnaire, does the prime contractor need to show cGMP manufacturing history or can an accomplished subcontractor serve this need? Should critical subcontractors such as manufacturing partners provide past performance questionnaires?**





Contract Questions Past Performance



- **What is the impact of Past Performance on the technical score, if a small business does not have all of the expertise cited (e.g., conducting large clinical trials, interactions with the FDA on Animal Rule)?**
 - *Past performance is rated separately and will not impact the Technical score.*



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Questions & Answers



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